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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,689	09/19/2003	James Lee	P0706P2C2D2C1	2217

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EXAMINER	
ULM, JOHN D	
ART UNIT	**PAPER NUMBER**
1649	

DATE MAILED: 10/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/666,689	LEE ET AL.	
	Examiner	Art Unit	
	John D. Ulm	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-73* is/are pending in the application.

4a) Of the above claim(s) *31-73* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/12/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1) Claims 20 to 73 are pending in the instant application. Claims 21 to 24, 26 to 39, 41 to 45, 47 to 52, 56 to 58 and 60 to 73 have been amended as requested by Applicant in the correspondence filed 15 August of 2005.

2) Claims 31 to 73 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the correspondence filed 15 August of 2005. The traversal is on the ground(s) that a restriction requirement is only proper when inventions are "independent and distinct". This is not found persuasive because this premise is completely in conflict with current patent practice as explained in M.P.E.P. 803 as follows:

803 Restriction - When Proper [R - 2]

Under the statute an application may properly be required to be restricted to one of two or more claimed inventions only if they are able to support separate patents and they are **either independent** (MPEP § 806.04 - § 806.04(j)) **or distinct**>(< MPEP § 806.05 - § 806.05(I)).

If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to distinct or independent inventions.

CRITERIA FOR RESTRICTION BETWEEN PATENTABLY DISTINCT INVENTIONS

There are two criteria for a proper requirement for restriction between patentably distinct inventions:

(1) The inventions must be independent (see MPEP § 802.01, § 806.04, § 808.01) or distinct as claimed (see MPEP § 806.05 - § 806.05(I)); and

(2) There must be a serious burden on the examiner if restriction is not required (see MPEP § 803.02 § 806.04(a) - (j), § 808.01(a) and § 808.02).

GUIDELINES

Examiners must provide reasons and/or examples to support conclusions, but need not cite documents to support the requirement in most cases.

Where plural inventions are capable of being viewed as related in two ways, both applicable criteria for distinctness must be demonstrated to support a restriction requirement.

If there is an express admission that the claimed inventions are obvious over each other within the meaning of 35 U.S.C. 103, restriction should not be required, In re Lee, 199 USPQ 108 (Deputy Asst. Comm'r. for Pats 1978).

For purposes of the initial requirement, a serious burden on the examiner may be prima facie shown if the examiner shows **by** appropriate explanation either **separate classification**, separate status in the art, or a different field of search as defined in MPEP § 808.02. That prima facie showing may be rebutted by appropriate showings or evidence by the applicant. Insofar as the criteria for restriction practice relating to Markush - type claims is concerned, the criteria is set forth in MPEP § 803.02. Insofar as the criteria for restriction or election practice relating to claims to genus - species, see MPEP § 806.04(a) - (j) and MPEP § 808.01(a).

Because Applicant's traversal is based upon a premise which is directly contrary to current patent practice as explained above and an initial search burden was shown by separate classification of the different inventions the requirement is still deemed proper and is therefore made FINAL.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3) Claims 20 to 30 are rejected under 35 U.S.C. § 101 because they are drawn to an invention with no apparent or disclosed specific and substantial credible utility. The instant claims are drawn to an isolated protein identified in the instant specification as "PF4AR". The instant application does not disclose a specific biological role for this protein or its significance to a particular disease, disorder of

physiological process which one would wish to manipulate for a desired clinical effect. As stated on page 53 therein, "[t]he polypeptides set forth in Figs. 4 and 5 are believed to represent receptors for different and as yet undetermined members of the PF4 superfamily" and that "[l]n preliminary experiments, recombinant cells bearing these receptors do not respond to Rantes, MCPI, IL-8 or MGSA, although they may ultimately be shown to bind other members of the PF4 superfamily or presently unknown ligands".

It is clear from the instant specification that the putative receptor protein described therein as "PF4AR" is what is referred to as an "orphan receptor" in the art. This is a protein whose cDNA has been isolated because of it encodes an amino acid sequence that is similar to that of one or more known receptor proteins or putative receptor proteins. There is little doubt that, after complete characterization, a receptor protein of the instant invention may be found to have a specific and substantial credible utility. This further characterization, however, is part of the act of invention and until it has been undertaken Applicant's claimed invention is incomplete. Whereas one could readily employ a putative receptor protein of the instant invention in an assay to identify ligands thereto the information obtained thereby would be of little use until one discovers the identity of those physiological processes moderated by the interaction of that ligand with that putative receptor. Because the instant specification has failed to credibly identify a physiological process which has been shown to be influenced by the activation or inhibition of a putative receptor protein of the instant invention an artisan would have no way of predicting what effects the administration of that ligand to an organism would have. If one can not predict the effects that the administration of a

ligand of the putative receptor of the instant invention is going to have on an organism then it is unclear as to what practical benefit is derived by the public from the identification of that ligand.

The instant situation is directly analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. § 101, which requires that an invention must have either an immediately obvious or fully disclosed "real world" utility. The court held that:

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", " [u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field", and "a patent is not a hunting license", " [i]t is not a reward for the search, but compensation for its successful conclusion."

The instant claims are drawn to an isolated protein of as yet undetermined function or biological significance, and the protein encoded thereby. There is absolutely no evidence of record or any line of reasoning that would support a conclusion that a protein of the instant invention is associated in any way with the plurality of immunological disorders that are listed on page 14 of the instant specification. Until

some actual and specific significance can be attributed to the protein identified in the specification as "PF4AR" the instant invention is incomplete. The protein of the instant invention is a compound known to be structurally analogous to proteins which are known in the art as G protein-coupled receptors. In the absence of a knowledge of the natural ligands or biological significance of this protein, there is no immediately obvious patentable use for it. To employ a protein of the instant invention in the identification of substances which inhibit or induce its activity is clearly to use it as the object of further research which has been determined by the courts to be a utility which, alone, does not support patentability. Since the instant specification does not disclose a credible "real world" use for "PF4AR" then the claimed invention is incomplete and, therefore, does not meet the requirements of 35 U.S.C. § 101 as being useful.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4) Claims 20 to 30 are rejected under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to use the instant invention for those reasons given above with regard to the rejection of these claims under 35 U.S.C. § 101.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5) Claims 20 to 30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims are vague and indefinite in so

far as they employ the term "PF4AR" as a limitation. Because the instant specification does not identify that property or combination of properties which is unique to and, therefore, definitive of a "PF4AR amino acid sequence" an artisan can not determine if a compound which meets all of the other limitations of a claim would then be included or excluded from the claimed subject matter by the presence of this limitation. For example, it is unclear how the limitation "the amino acid sequence of Figure 5" differs in scope from "the PF4AR amino acid sequence of Figure 5". Whereas an Artisan could readily determine the metes and bounds of the first limitation, that artisan can not determine what additional material is encompassed or excluded by the presence of the term "PF4AR".

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6) Claims 25 and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by the Kobilka et al. publication (SCIENCE 238:650-656, 30 Oct., 1987). These claims are drawn to an isolated polypeptide comprising AN EXTYRACELLULAR region of SEQ ID NO:6. A region of an amino acid sequence can correspond to as little as a single amino acid. Therefore, these claims encompass any isolated polypeptide comprising any single amino acid that occurs in an extracellular portion of SEQ ID NO:6., which includes the residues methionine, aspartic acid, leucine, glutamic acid, asparagine, tyrosine, proline, arginine, threonine, phenylalanine and tryptophan, all of

which can be found in the extracellular "N-terminal fragment' of SEQ ID NO:6. These claims encompass essentially any and all isolated polypeptides, including the receptor protein of Kobilkaq et al., because virtually all polypeptides comprise one or more of those eleven different amino acids that are present in the extracellular "N-terminal fragment" of SEQ ID NO:6..

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (571) 272-0880. The examiner can normally be reached on 9:00AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JOHN ULM
PRIMARY EXAMINER
GROUP 1800